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FRIDAY, MAY 19, 1978
PART IV

CONSUMER PRODUCT SAFETY COMMISSION

BENZENE

Regulation as an Intentional Ingredient or as a Contaminant; Products Requiring Special Labeling; and Substances Requiring Special Packaging

[6355-01]

CONSUMER PRODUCT SAFETY COMMISSION

[16 CFR Part 1145]

CONSUMER PRODUCTS CONTAINING BENZENE AS AN INTENTIONAL INGREDIENT OR AS A CONTAMINANT UNDER THE CONSUMER PRODUCT SAFETY ACT

Proposed Rule to Regulate

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: The Commission proposes to regulate consumer products, except gasoline and solvents or reagents for laboratory use, containing benzene as an intentional ingredient or as a contaminant, under the Consumer Product Safety Act (CPSA) instead of under the Federal Hazardous Substances Act (FHSA), to address the risks of blood disorders, chromosomal abnormalities, and leukemia associated with benzene inhalation. According to the CPSA, the Commission may not regulate under the CPSA a risk of injury that could be eliminated or reduced to a sufficient extent under the FHSA, unless the Commission finds by rule that it is in the public interest to do so. The Commission has preliminarily found that it is in the public interest to regulate these products under the CPSA.

DATE: Comments concerning this proposal must be received by June 30, 1978. It is expected that this rule will become effective when any final CPSA rule concerning benzene is effective.

ADDRESS: Comments should be sent to: Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207.

FOR FURTHER INFORMATION CONTACT:

Francine Shacter, Office of Program Management, Consumer Product Safety Commission, Washington, D.C. 20207, 301-492-6557.

SUPPLEMENTARY INFORMATION: The purpose of this notice is to propose a rule under section 30(d) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2079(d), to regulate consumer products, except gasoline and solvents or reagents for laboratory use, containing benzene as an intentional ingredient or as a contaminant, under the CPSA. Although the risk of injury from blood disorders, chromosomal abnormalities, and leukemia associated with these products could be eliminated or reduced to a sufficient extent by action under the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261-1274, the Commission has preliminarily determined that it is in the public interest to regulate these products under the CPSA.

The Commission believes it is in the public interest to regulate these benzene-containing products under the CPSA rather than the FHSA, since the rulemaking proceedings appropriate to regulate these products under the FHSA are likely to be lengthy and resource-consuming.

The Commission also believes it is in the public interest to regulate these products under the CPSA since it may be more difficult for interested persons to participate in rulemaking proceedings under the FHSA than the CPSA because the proceedings under the FHSA are likely to be more complex and formal.

In order to ban hazardous household substances under section 2(q)(1)(B) of the FHSA, the Commission must follow the provisions of section 701(e) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 371(e). Section 701(e) of the FFDCA provides for a two stage rulemaking. After the Commission proposes a regulation, analyzes comments, and issues a final regulation, adversely affected persons may submit objections to the rule and request a public hearing on the objections. If the objections are legally valid, those parts of the regulation objected to are stayed and a hearing is held to receive evidence that is relevant and material to the issues raised by the objections.

After completion of the hearing, the Commission may issue a final regulation. However, this regulation must be based on substantial evidence of record obtained at the hearing, and must set forth detailed findings of fact on which the order is based. The Commission's past experience with formal rulemaking under section 701(e) has been that these proceedings are lengthy, resource-consuming, and often inefficient in eliciting information on which the Commission may make a decision.

In contrast, section 9(a)(2) of the CPSA requires bans to be issued in accordance with the informal rulemaking provisions of the Administrative Procedure Act (5 U.S.C. 553). Although the CPSA requires the Commission to provide an opportunity for oral presentation of comments before issuing a ban, the oral presentation required by section 9(a)(2) is informal and nonadversarial. A ban under section 8 of the CPSA, while providing an adequate opportuity for public participation, is less likely to involve extensive delay, since the Commission is not required to utilize formal rulemaking. In addition, since the proceedings under section 8 of the CPSA are less complex and formal than those under the FHSA, the Commission is more likely to obtain participation from interested persons including consumers, than if the rulemaking is conducted under the FHSA.

The Commission has also preliminarily determined that it is in the public interest to regulate consumer products containing benzene as an intentional ingredient or as a contaminant under the CPSA rather than the FHSA, since the CPSA, unlike the FHSA, provides that persons who knowingly violate the act are subject to civil penalties. The civil penalty provision may provide additional incentive for compliance under the CPSA.

However, if the Commission does decide to regulate these products under section 8 of the CPSA, the Commission recognizes that automatic repurchase of banned hazardous products would not be available, as it is in the case of a ban under the FHSA. Under section 15 of the FHSA, 15 U.S.C. 1274, and the accompanying regulations at 16 CFR 1500.202 and .203, hazardous substances that have been banned must be repurchased by the manufacturers, distributors, and retailers of the hazardous substance, regardless of whether the substance was banned at the time of its sale. In contrast, a rule under section 8 of the CPSA that bans products distributed in commerce or manufactured after the effective date of the ban would not provide for repurchase of the banned hazardous products.

Elsewhere in this FEDERAL REGISTER the Commission has proposed a ban of benzene-containing consumer products under section 8 of the CPSA.

PROPOSAL

The Commission, therefore, proposes below to regulate consumer products, except gasoline and solvents or reagents for laboratory use, containing benzene as an intentional ingredient or as a contaminant under the CPSA instead of the FHSA.

Accordingly, pursuant to provisions of the Consumer Product Safety Act (section 30(d), Pub. L. 92-573, 86 Stat. 1231, as amended 90 Stat 510; 15 U.S.C. 2079(d)), the Commission proposes that title 16, chapter II, subchapter B, part 1145 be amended by adding the following new § 1145.6.

§ 1145.6 Consumer products, except gasoline and solvents and reagents for laboratory use, containing benzene as an intentional ingredient or as a contaminant; risk of blood disorders, chromosomal abnormalities, and leukemia associated with benzene inhalation.

The Commission finds that it is in the public interest to regulate the risk of injury from blood disorders, chromosomal abnormalities and leukemia associated with benzene inhalation under the Consumer Product Safety Act rather than the Federal Hazardous Substances Act because of the desirability of avoiding possibly lengthy, resource-consuming, and inefficient

rulemaking proceedings under the FHSA and because of the availability of civil penalties under the CPSA.

The Commission also believes that the complexity and formality of the rulemaking proceedings under the FHSA, in contrast to rulemaking proceedings under the CPSA, may make it difficult for interested persons to participate.

Therefore, consumer products, except gasoline and solvents and reagents for laboratory use, containing benzene as an intentional ingredient or as a contaminant shall be regulated under the CPSA.

(Sec. 30(d), Pub. L. 92-573, 86 Stat. 1231, as amended, 90 Stat. 510 (15 U.S.C. 2079(d)).)

Interested persons are invited to submit, on or before June 30, 1978, written comments regarding this proposal. Written comments and any accompanying data or material should be submitted preferably in five copies, addressed to the Secretary, Consumer Product Safety Commission, Washington, D.C. 20007. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the Office of the Secretary, Third Floor, 1111 18th Street NW., Washington, D.C. during working hours Monday through Friday.

Dated: May 15, 1978.

SADYE E. DUNN,
Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 78-13592 Filed 5-18-78; 8:45 am]

[6355-01]

[16 CFR Part 1307]

CONSUMER PRODUCTS CONTAINING BENZENE AS AN INTENTIONAL INGREDIENT OR AS A CONTAMINANT

Proposal to Ban

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: The Commission proposes to ban all consumer products, except gasoline and solvents or reagents for laboratory use, containing benzene, as an intentional ingredient or as a contaminant at a level 0.1 percent or greater by volume. The Commission is taking this action because of information indicating that benzene inhalation may cause blood disorders, chromosomal abnormalities, and leukemia or cancer of the whitle blood cells in consumers exposed to benzene-containing products. The Commission is particularly interested in public comment on the proposed contaminant level and on the issue of health effects of all potential benzene substitutes. In taking this action, the Commission is granting a petition (HP77-12) from the Health Research Group.

DATES: (1) Written comments on the proposal must be received by June 30, 1978. (2) There will be an opportunity for interested persons to orally present data, views, or arguments on June 14, 1978, at 9:30 a.m. Those wishing to make oral presentations should notify the Office of the Secretary by June 7, 1978. Additionally, a summary or copy of testimony is to be submitted to the Office of the Secretary two working days prior to the public meeting. (3) The Commission proposes that consumer products containing benzene as an intentional ingredient manufactured or imported 60 or more days after publication of the final rule in the FEDERAL REGISTER be declared banned hazardous products. Alternatively, the Commission is proposing a shorter effective date with retrospective application for products containing intentionally-added benzene. Under this option, consumer products containing intentionally-added benzene which are initially introduced into interstate commerce 15 or more days after publication of a final rule would be banned hazardous products. All other consumer products containing intentionally-added benzene, no matter when manufactured or initially introduced into commerce, would be banned 30 days after publication of a final ban. As to products that contain benzene as a contaminant, it is expected that the ban will apply to all such products which are manufactured or imported after the date which is 120 days after publication of the final rule. (4) The time during which the Commission must either publish a final rule or withdraw this proposal is extended to October 16, 1978.

ADDRESSES: Written comments should be submitted to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207. To the extent practicable, comments on the issue of benzene as an intentional ingredient should be separated from comments on the issue of benzene as a contaminant. Persons wishing to make oral presentations should contact Richard Danca in the Office of the Secretary. These oral presentations will be held in the Commission's 3rd floor hearing room at the address below. All material which the Commission has that is relevant to this proceeding, including any comments that may be received regarding this proposal, may be seen in, and copies obtained from, the Office of the Secretary, Consumer Product Safety Commission, 3rd floor, 1111 18th Street NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT:

Francine Shacter, Office of Program Management, Consumer Product Safety Commission, Washington, D.C. 20207—202-492-6557. Persons wishing to make oral presentations should contact: Richard Danca, Office of the Secretary, 202-634-7700.

SUPPLEMENTARY INFORMATION:

BACKGROUND

On May 5, 1977 the Commission received a petition (HP 77-12) from the Health Research Group requesting that the Commission declare benzene a banned hazardous substance under the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261 et seq., and remove all products containing benzene from the marketplace because of evidence that benzene causes leukemia. The petitioner note that new evidence linking worker exposure to benzene to the induction of leukemia had prompted the Occupational Safety and Health Administration (OSHA) to publish an Emergency Temporary Standard (ETS) for benzene on May 3, 1977 (42 FR 22516). HP 77-12 was later supplemented by a statement in support of the petition from Dr. Michael McCann of the Center for Occupational Hazards, Inc. Dr. McCann expressed particular interest in the banning of benzene-containing art supplies used by consumers.

In gathering information on HP 77-12, Commission staff attended hearings sponsored by OSHA which covered their ETS as well as the OSHA proposed permanent standard for benzene (42 FR 27452; May 27, 1977). The OSHA hearings, which began on July 19, 1977 and were held on successive work days through August 10, 1977, included testimony on health, economic, and environmental issues relevant to the OSHA regulations.

Based on information gathered from the OSHA hearings and from other sources, discussed more fully below, the Commission has granted the petition and proposes to ban all consumer products, except gasoline and solvents or reagents for laboratory use, containing benzene as an intentional ingredient. The Commission also proposes to ban all consumer products containing benzene as a contaminant at a level of 0.1 percent or greater by volume. The Commission is taking this action because of scientific and technical information indicating that benzene inhalation may cause blood disorders, chromosomal abnormalities, and leukemia in consumers exposed to benzene-containing products. While the Commission recognizes that much of the data discussed below concern benzene exposure in an industrial setting, the Commission points out that it does have some information concerning consumer exposure. In addition, the Commission points out that there is general scientific and medical agreement that there is no known safe level

of exposure to a carcinogen and that such exposure should, therefore, be reduced to the lowest feasible level.

Although the petition was filed under the FHSA and it appears that the risk of injury from leukemia described by the petitioner is regulatable under the FHSA, the Commission proposes to ban benzene-containing products under the Consumer Product Safety Act (CPSA), 15 U.S.C. 2051, et seq. Section 30(d) of the CPSA, 15 U.S.C. 2079(d), as amended, provides that a risk of injury associated with a consumer product which can be eliminated or reduced to a sufficient extent by action under a transferred act, such as the FHSA, may nonetheless be regulated under the CPSA if the Commission, by rule, determines that regulation under the CPSA is in the public interest. Also published in this issue of the FEDERAL REGISTER is a proposed rule issued in accordance with section 30(d) of the CPSA stating the Commission's finding that it is in the public interest to ban the products described herein under the CPSA.

Current Commission regulations under the FHSA (see 16 CFR § 1500.14 (a)(3) and (b)(3)) require that products containing 5 percent or more by weight of benzene must be specially labeled with the signal word "danger", the word "poison", the skull and crossbones symbol, and the statement of the hazard "vapor harmful." Products containing 10 percent or more by weight of benzene must bear the additional statement of hazard "harmful or fatal if swallowed" as well as the statement "If swallowed, do not induce vomiting. Call physician immediately."

The Commission also has a regulation under the Poison Prevention Packaging Act of 1970 (PPPA) applicable to benzene. (16 CFR § 1700.14(a)(15)). The regulation provides that solvents for paints and other similar surface-coating materials that contain 10 percent or more by weight of benzene and that have a viscosity of less than 100 Saybolt Universal Seconds (SUS) at 100° F must be packaged in child-resistant packaging.

Elsewhere in this issue of the FEDERAL REGISTER, the Commission is proposing to amend the FHSA and PPPA regulations to indicate that they will not be applicable to products that are banned hazardous products under any final CPSA rule. The amendments are proposed to be effective when this Part 1307 becomes effective.

OTHER AGENCY ACTION

The Commission notes that other federal agencies have taken action with respect to benzene. As mentioned above, on May 27 1977, OSHA published its proposed permanent standard for benzene which would limit employee exposure to benzene to 1 ppm as an 8 hour time-weighted average concentration with a ceiling level of 5 ppm for any 15 minute period during an 8 hour day. The proposed standard excluded operations in which the only exposure to benzene is from liquid mixtures which contain no more than 1 percent or less of benzene by volume (0.1 percent after one year from the effective date). (42 FR 27452). On February 10, 1978, OSHA published its final permanent standard for benzene limiting employee exposure to the same levels announced in the proposal. However, the percentage exemption for liquid mixtures containing benzene was dropped because OSHA found that the percentage of benzene in a liquid is not necessarily controlling of an employee's exposure level. Thus, the final standard applies to all liquid mixtures containing benzene regardless of the percent of benzene.[1] The standard also provides for the measurement of employee exposure, engineering controls, work practices, personal protective clothing and equipment, signs and labels, medical surveillance, and employee training (see 42 FR 5918).

In addition to the OSHA action, the Commission notes that the Environmental Protection Agency (EPA) on June 8, 1977 published its decision to list benzene as a hazardous air pollutant under section 112 of the Clean Air Act on the basis of scientific reports which strongly suggest an increased incidence of leukemia in humans exposed to benzene (42 FR 29332).

BENZENE'S PROPERTIES AND USES

Benzene (C_6H_6), also known as Benzol, is a clear, colorless, strong-smelling liquid which is extremely flammable. Benzene has a low boiling point and a high vapor pressure and hence evaporates rapdily under ordinary atmospheric conditions, giving off vapors nearly three times heavier than air. It has significant solvent properties and mixes well with the majority of organic solvents. Benzene occurs naturally in crude oil and also as a product of decomposition of organic material.

Today, benzene is used primarily as an intermediate substance in the production of other chemicals. Cumene, cyclohexane, dichlorobenzene, dodecylbenzene, ethylbenzene, maleic anhydride and nitrobenzene are a few of these chemicals. Additionally, benzene is used as a component of unleaded gasoline to increase the octane rating, as a solvent and reactant in numerous chemical applications in laboratories, and in the manufacture of detergents and pesticides. Benzene is predominantly produced today from petroleum by catalytic reformation.

Benzene's characteristics as a solvent have made it figure prominently over the years in the manufacture of consumer products. It has been used in its pure form in some products and in other products as a component of solvents that are used in manufacturing the final product. Based on Commission staff communications with manufacturers, the consumer products which have been identified as containing benzene as an intentional ingredient are paint removers, rubber cements, gasoline, and solvents and reagents for laboratory use. Other products, notably many products containing petroleum distillates, which include many common solvents such as toluene and naphtha, contain benzene as a contaminant. (For further discussion, see the section of this Preamble entitled ECONOMIC CONSIDERATIONS).

NATURE AND DEGREE OF THE RISK OF INJURY

Benzene has long been recognized as a toxic substance capable of producing acute and chronic effects. Inhalation is the primary route of exposure to a human being. Although present evidence suggests that benzene is not readily absorbed through the skin, significant quantities of benzene could be absorbed in the case of injured skin.

The acute effects of benzene exposure include drowsiness and loss of consciousness at high doses. The chronic effects of benzene exposure, which form the basis for this proposed regulation, are detailed below in a technical report on benzene prepared by a Commission consultant, Michael L. Freedman, M.D. of New York University Medical Center. The chronic effects listed in the report fall into three general categories: (1) pancytopenia (a decrease in all the formed elements of the blood—red cells, white cells, and platelets); (2) chromosomal abnormalities; and (3) leukemia, particularly acute myelogenous (produced in the bone marrow) leukemia.

The Freedman report and accompanying bibliography is set forth in its entirety as an appendix to this document. That report discusses the many studies reported in the scientific literature which have implicated benzene exposure in the development of various blood disorders, including leukemia, and chromosomal abnormalities. The Commission has considered this report along with other available information in proposing the ban and makes the following observations.

(1) Pancytopenia, including aplastic anemia, has been demonstrated in

[1] On March 28, 1978 (43 FR 12890), OSHA proposed to amend the final benzene standard to exclude from its coverage work operations where the sole exposure to benzene is from liquid mixtures containing 0.1% or less benzene or the vapors from these liquids. At the same time OSHA stayed the benzene standard to the extent it covers such work operations, pending completion of the rulemaking and proceedings on the amendment.

both humans and animals following exposure to benzene, although it has not been observed subsequent to exposure to other compounds, such as toluene and xylene, which are commonly associated with benzene environmentally. Both pancytopenia and aplastic anemia, although they are non-cancerous diseases, may themselves be fatal. An additional concern is that some or all of the blood disorders induced by benzene may, if allowed to continue, either progress to or represent a preluekemic stage which may eventually evolve into an actual leukemia.

(2) The development of various chromosomal aberrations, both stable and unstable in nature, in peripheral leukocytes and bone marrow cells have been attributed to benzene exposure.

(3) Leukemia is the most serious blood disorder associated with benzene exposure. Once leukemia is diagnosed, there is virtually no chance of recovery. Despite advances in leukemia therapy, the prognosis of acute myelogenous leukemia (the most prevalent subtype of leukemia in adults and the type most commonly associated with benzene) remains poor. OSHA in their permanent benzene standard states that the average life expectancy of even the victims who enter into a remission (generally averaging 6–8 months) ranges from 12–18 months. (43 FR 5925).

Latency periods between exposure to benzene and development of leukemia can vary widely, ranging from two to twenty years. However, leukemia has been observed in workers exposed for as little as four months to benzene or for as much as 15 years or longer. Individual susceptibility to the effects of benzene also varies significantly. In a recent study of workers exposed to benzene from 1940–1949 in two Ohio plants manufacturing the product "Pliofilm", Infante (see reference No. *51* in Freedman bibliography) demonstrated a five-fold excessive risk of death from all leukemias and a ten-fold excess of deaths from myeloid and monocytic leukemias in the study population compared with the number expected in a non-exposed cohort. Infante stated that benzene concentrations at the two plants ranged from 0 to 10 or 15 parts per million. This study as well as other occupational studies noted in the Freedman report argue convincingly that benzene is a human leukemogen.

The Commission recognizes that much of the documentation in the consultant's report concerns benzene exposure in an industrial setting. However, as the report indicates, in 1977 the National Institute for Occupational Safety and Health conducted an experiment to measure the amount of benzene exposure to a person using a paint remover containing 52 percent benzene by volume (Reference No. *137*). An end table was stripped in a home garage having essentially no air circulation. Five sequential, five minute air samples from the worker's breathing zone were taken. The benzene concentration ranged from 73 to 225 ppm with a mean of 130 ppm. In addition, the Commission notes that values from 1971 exist for exposure levels in one man or husband-wife combination commercial paint stripping operations utilizing paint strippers containing approximately 40 percent benzene. The breathing zone average atmospheric concentration of benzene ranged from 24 to 1216 ppm in 8 such establishments. (Reference No. *138*).

In view of the data indicating that blood disorders, including leukemia, have been shown to result from benzene exposure in an industrial setting at levels reported to be as low as 10—15 ppm, the Commission believes that a serious health hazard to consumers may be presented by the use of benzene-containing consumer products.

As an additional matter, the Commission's Health Sciences staff has calculated an assessment of the leukemia risk from consumer exposure to benzene-containing paint strippers. The assessment which uses data from the Infante study discussed above and the NIOSH paint stripper experiment also discussed above is on file at the Commission's Office of the Secretary. For purposes of this assessment, the Commission considered the use of a paint stripper containing 52 percent benzene by a consumer, for 5 hours a day ten times in his life, to be a reasonably foreseeable lifetime exposure. The increased lifetime risk of death from myelogenous and monocytic leukemia induced by this exposure is estimated by the assessment at between 142 and 346 per million exposed.

This is equivalent to a benzene-induced increased risk of between 15.2 percent and 37.1 percent due to the use of such paint strippers. While the Commission is not relying upon a specified percentage of increased risk in issuing this ban, the Commission believes that in view of the seriousness of the risks of injury from benzene exposure, any increased risk is unacceptable.

In addition, the Commission emphasizes that once the carcinogenicity of a substance has been established qualitatively, any exposure must be considered to be attended by risk when considering any given population, because individual susceptibility to a carcinogen varies widely. The Commission, therefore, believes that consumer exposure to benzene at low levels poses a carcinogenic risk to certain individuals. In recognition of the present state of scientific knowledge that there is no known safe level of exposure to a carcinogen, the Commission concludes that it is appropriate that exposure to benzene be reduced to the lowest feasible level.[2] (For further discussion on this point, see the section of the preamble entitled DESCRIPTION OF THE PROPOSED BAN.)

Description of the Proposed Ban

Proposed Part 1307 would declare that consumer products containing benzene as an intentional ingredient are banned hazardous products under section 8 of the CPSA. Consumer products that contain benzene as an impurity at a level of 0.1 percent or greater by volume would also be declared to be banned hazardous products. For purposes of this Part 1307, "benzene as an intentional ingredient" means benzene which is added deliberately to a product to impart specific characteristics. "Benzene as a contaminant" is any benzene appearing in a final product which is not an intentional ingredient, including any benzene which appears as a component of or impurity in a raw material used in the final product.

The proposed ban applies to products that are customarily produced or distributed for sale to or for the personal use, consumption or enjoyment of consumers in or around a household or residence, a school, in recreation or otherwise. The Commission proposes that consumer products containing benzene as an intentional ingredient manufactured or imported 60 or more days after the publication of the final rule in the Federal Register be declared banned hazardous products. Alternatively, the Commission is proposing a shorter effective date with retrospective application for products containing intentionally-added benzene. Under this option, consumer products containing intentionally-added benzene which are initially introduced into interstate commerce 15 or more days after publication of a final rule would be banned. All other consumer products containing intentionally-added benzene, no matter when manufactured or initially introduced into commerce, would be banned 30 days after publication of a final rule. For

[2] The National Cancer Institute's Ad Hoc committee on the Evaluation of Low Levels of Environmental Carcinogens (1970) has stated: "no level exposure to a chemical carcinogen should be considered toxicologically insignificant for man. For carcinogenic agents, a safe level for man cannot be established by application of our present knowledge." (cited in the OSHA permanent benzene standard at 43 FR 5947). In addition, Bernard Goldstein, M.D. and Muzaffer Askoy, M.D., experts in the field of benzene toxicity, both testified before OSHA that there is no known safe level of exposure to benzene and that, therefore, any exposure should be reduced to the lowest feasible level. (See 43 FR 5947.)

products containing benzene as an impurity, it is expected that the ban will apply to all such products which are manufactured or imported after the date which is 120 days after publication of the final rule.

Gasoline is exempted from the products banned by the proposal. While most gasoline is specifically for use with motor vehicles and would appear to be considered "motor vehicle equipment" excluded from Commission authority under the CPSA (see section 3(a)(1)(C)), the Commission notes that some gasoline is used by consumers "in or around a permanent or temporary household or residence, a school, in recreation, or otherwise." For instance, gasoline is often sold to consumers for use as a general household solvent or for use with lawn mowers, snowmobiles, and so forth, and the Commission possibly could take regulatory action under the CPSA as to this gasoline. However, since this gasoline generally comes from the same source (i.e. the retail pumps) as motor vehicle gasoline and may be subject to regulation by OSHA, EPA, and/or the National Highway Traffic Safety Administration (NHTSA), the Commission is of the opinion that exposure to benzene from gasoline is a complex interagency problem which would probably best be resolved on an interagency basis.

In addition, the Commission believes that any attempt to eliminate benzene from gasoline would have a major economic impact, necessitating thorough feasibility studies which are beyond the scope of this propsoal. In this regard the Commission notes that benzene is present in gasoline as a contaminant and in unleaded gasoline, as an intentional ingredient used to increase the octane rating. The use of benzene and its closely related aromatic distillates, xylene and toluene, has increased in the past few years because the distillates are the principal substitutes for tetraethyl lead. The Commission has information indicating that the removal of benzene from gasoline motor fuel would entail major adjustments in the petroleum refining industry in terms of capital equipment and performance and price and availability of gasoline as well as other petrochemicals and has, therefore, concluded that the use of benzene in consumer product gasoline should not be restricted at this time. The Commission emphasizes, however, that the complexity of the gasoline question need not delay Commission action on other benzene-containing products.

Besides exempting gasoline, the proposed ban contains an exemption for benzene manufactured and distributed for use in laboratories as a solvent or a reagent. Because benzene is the basic unit on which aromatic hydrocarbon chemistry is built and can be expected to be found in nearly pure form in school laboratories at the high school, college, and graduate levels, the Commission has decided to propose an exemption for such laboratory benzene. The Commission notes that it has information indicating that benzene is essential for certain experiments at the junior and senior college level as well as at the graduate level. The Commission believes that where careful laboratory procedures are followed, such as the use of properly functioning hoods and other appropriate practices, exposure to benzene vapors should be very low. (See OSHA's permanent standard for the regulation of benzene, 43 FR 5918, at 5938.)

In this regard, the Commission points out that OSHA's permanent benzene standard covers benzene exposure in research facilities in both industrial and academic laboratories, where there is at least one employee. All containers of benzene in such laboratories are required to be bear specified labeling, warning of the cancer hazard. In addition, laboratories must comply with all other provisions of the performance standard, which, as is explained in the preamble to the standard, could be met by laboratories in many instances through the use of properly designed hoods. Therefore, the Commission believes that an absolute exemption for laboratory benzene is appropriate because students in educational laboratories using benzene will be protected by the requirements of the OSHA standard.

It should be noted that the proposed ban not only affects products which contain benzene as an intentional ingredient, but also products which contain benzene as a contaminant. In recognition of the medical and scientific agreement that there exists no known safe level of exposure to a carcinogen, the Commission believes that consumer exposure to carcinogens such as benzene must be reduced to the lowest feasible level. The Commission, further, believes that with respect to benzene, the lowest feasible level is not zero, but some low level of benzene contamination in products. (Note: With consumer exposure, unlike occupational exposure, standards based on air monitoring procedures or a requirement for sophisticated protective equipment are impractical. The Commission, therefore, has not attempted to set a permissible air concentration level for benzene, but proposes to rely instead on a percentage limitation on benzene in products.)

The reason that benzene cannot be eliminated entirely from all products is because of the physical properties of petrochemical refining process. As has been mentioned above, benzene occurs naturally in crude oil. It is also formed in the petrochemical refining process as part of a product called reformate from which gasoline and other petroleum products are distilled. These products are distilled into various petroleum distillate fractions according to boiling point range. The boiling point ranges tend to be fairly crude in normal refinery practice so that any particular distillate may have residual or contaminant fractions with boiling points both above and below it. The purity of the distillate depends on the age and technical sophistication of each refinery operation. Additional refining steps may be performed on the distillate in order to strip away the contaminating fractions.

The Commission recognizes that without resorting to extremely expensive special techniques, these refining processes do not result in chemically pure products. The Commission is also aware that reduction of contaminants below the lowest levels generally available in commerce would entail very expensive changes in refinery equipment throughout the industry. Therefore, the Commission proposes to set as the lowest feasible level of benzene contamination, the lowest level generally available in commerce.

Economic information available to the Commission indicates that most common solvents or petroleum distillates which may show traces of benzene contamination are generally available with less than 0.1 percent benzene contamination. Manufacturers, furthermore, substitute one distillate for another or use various combinations of distillates, with a high degree of flexibility. (See "Economic Assessment of a Potential CPSC Benzene Regulation" on file at the Commission's Office of the Secretary). While some benzene substitutes are available with benzene contamination considerably lower than 0.1 percent and others have a higher contamination level (see Table 1 below), the Commission has selected the 0.1 percent level as representative of a feasible impurity level. In so doing, the Commission has preliminarily concluded that it is not now technically feasible to avoid a level of benzene contamination in consumer products below 0.1 percent and has, therefore, decided to propose a ban of products containing benzene traces at or above the level.

While the Commission's current information indicates that contamination below 0.1 percent is the lowest feasible impurity level for benzene in products, the Commission, in recognition of the limited information available on benzene as a contaminant, particularly wishes to solicit public comment on the issue of an appropriate level and the costs of achieving various levels. Based on the comments and other relevant material which may be received in response to the proposal, the Commission may revise

the allowable impurity level when the ban is finalized.

ECONOMIC CONSIDERATIONS

Information available to the Commission indicates that the only consumer products which currently contain benzene as an intentional ingredient are paint removers, rubber cements, gasoline, and solvents and reagents for laboratory use. It appears that the OSHA regulations have resulted in a reduction of the use of benzene in consumer products. In fact, only a few firms are using benzene in their consumer products. Since benzene is produced and sold predominantly for industrial use, it is expected that CPSC action will not have a major impact on producers of benzene.

The paint remover industry is one of two industries likely to be affected by a CPSC ban. (As noted above, gasoline and laboratory benzene are proposed to be exempted from the ban.) Generally, there has been a widespread movement away from the use of benzene in paint removers. Commission staff contact with 49 firms revealed only 2 firms presently using benzene in their paint removers. Commission staff estimates that less than 1 percent of the paint removers currently on the market contain benzene as an intentional ingredient.

The reformulation of removers involves the substitution for benzene of various combinations of methylene chloride, toluene, chlorinated hydrocarbons, mineral spirits, or other solvents. Most manufacturers agree that methylene chloride, usually used in conjunction with other solvents, makes a better remover than those currently produced with benzene. However, methylene chloride is a good deal more expensive than benzene. Other solvents which may be substituted for benzene—toluene, for example—will yield a less effective product for approximately the same price. In general, the economic impact on consumers of a ban will be in the form of price increases or utility losses, depending upon which solvent is substituted for benzene.

A ban on benzene-containing products is expected to have a minimal impact on the manufacturers of paint removers. For the few firms that still use benzene in the removers, there may be additional costs associated with reformulation, but these are expected to be small.

The rubber cement industry is another industry likely to be affected by a CPSC ban. In recent years there has been a steady decline in shipments of rubber cement, both in absolute terms and as a proportion of total adhesives shipments. From 1963 to 1973, shipments fell from $87 million to $55 million. During the same period, shipments of adhesives rose from $353 million to $820 million. This implies an absolute decrease in demand for rubber cement, probably in response to the substitution of other adhesives for comparable applications.

Of 52 rubber cement producers contacted, ony one is currently using benzene in his product. Commission staff estimates that less than 0.1 percent of the rubber cements on the market contain benzene. Reformulation costs are, furthermore, expected to be negligible.

Other consumer products such as varnish, wood stains, and household cleaners were investigated by Commission staff to determine whether benzene was present as an intentional ingredient. The products were found not to contain benzene, except possibly as a solvent impurity. Benzene, of course, is also used in almost a pure form in scientific laboratories as a solvent or a reagent. Such benzene is proposed to be exempt from Part 1307.

In addition to products containing intentionally added benzene, products which contain benzene as a contaminant at a level of 0.1 percent or greater are affected by the proposed ban. Many common solvents show traces of brenzene contamination. In fact, any petroleum distillate, even a highly refined solvent, will contain traces of benzene, because of the physical properties of the petroleum refining process. Since there appears to be a wide range of petroleum distillates or solvents generally available with benzene contamination of less than 0.1 percent, it is not expected that the ban on products containing benzene as an impurity will be burdensome to manufacturers or consumers. (See Table 1 below.)

TABLE 1.—*Typical benzene impurities*

	Percent	PPM
Heptane	0.0025	25
Hexane	.5	5,000
Mineral spirits	.1	1,000
Methyl ethyl ketone		0
Methylene chloride		0
Naphtha	.1	1,000
Toluene	.02	200
Xylene	.0025	25

Source: Various industry sources.

As noted above, a ban on consumer products containing benzene will necessitate the use of alternate solvents in manufacturing these products, many of which are other petroleum distillates. Possible substitutes are noted in the chart above. These solvents, with the exception of methylene chloride, are generally not as efficient as benzene, but are accceptable substitutes in most cases. The potential health effects of the use of these substitutes, however, is an issue which the Commission believes merits further study. While the Commission has some information on the health effects of potential substitutes which is summarized below, the Commission believes further information is necessary and specifically requests comment on the subject.

The Commission notes that although conflicting evidence exists, it appears that toluene and xylene may be slightly more acutely toxic than benzene. However, because toluene and xylene are not as volatile as benzene, less of these chemicals may be available in the atmosphere for exposure. (See International Labour Office. "Benzene users, toxic effects, substitutes." Geneva, May 16–19, 1967, pp. 48–89.) Neither toluene nor xylene appear to present the same chronic hazards as benzene. The "Benzene Health Effects Assessment", published as an external review draft in 1977 by the Environmental Protection Agency, states:

> Hematoxicity, particularly pancytopenia, has been observed in both humans and animals, following exposure to benzene. The toxicity does not folllow exposure to other compounds such as toluene and xylene commonly associated with benzene environmentally. (p. 2).

The Commission notes that a review of the scientific literature on benzene indicates that outbreaks of pancytopenia have followed the introduction of benzene to the workplace and have ceased when benzene has been substituted for by other solvents.

Methylene chloride has been for many years the standard active ingredient in paint removers. It is also a likely substitute for benzene in paint remover reformulations. However, it has been noted that methylene chloride, when inhaled, forms carbon monoxide in the body which reduces the blood's potential to carry oxygen and causes stress on the heart. Therefore, the use of methylene chloride-containing products by heart patients or heavy smokers may cause severe illness or even death. (Stewart and Hake, "Paint-Remover Hazard" in JAMA 235: 398–401, 1976). (In a separate matter, the Commission is considering the possibility of requiring special labeling on paint removers containing methylene chloride to warn of this hazard.)

Significant questions have also been raised concerning the potential chronic toxicity of methylene chloride. Long-term animal testing is now being conducted by the Dow Chemical Company and by the National Cancer Institute in an attempt to ascertain whether methylene chloride poses a potential carcinogenic hazard. Results from one of these laboratories should be available shortly. In addition, methylene chloride has been shown to be mutagenic in two types of short-term tests. (See, Proceedings of the 2nd International Conference on Environmental Mutagens: Progress in Ge-

netic Toxicology—Scott, D., Bridges, B. A., Sobells, FH., eds., Elsevier, North Holland (1977), pp. 249-258.) Further, the Toxic Substances Control Act (TSCA) Interagency Testing Committee has recently recommended to the Administrator of the Environmental Protection Agency that methylene chloride be added to the list of chemicals recommended for priority testing under TSCA. Because of these serious health concerns, the Commission particularly solicits comment on the toxicity of methylene chloride.

The Commission staff economic analysis and supporting materials are available from the Office of the Secretary.

ENVIRONMENTAL CONSIDERATIONS

An assessment has been made of the potential environmental impact of the proposed ban, as required by the National Environmental Policy Act. Based on this assessment, the Commission concludes that there are no significant environmental effects associated with the proposed and that no environmental impact statement is necessary.

The use of benzene as an ingredient in consumer products other than in gasoline and solvents and reagents for laboratory use has decreased over the years to the point where only a few small firms continue to use it. The reasons for this decline are a recognition of the health effects of benzene, the declining maximum allowable exposure limits imposed by State and federal health authorities, and the increased use of benzene as a valuable petro-chemical feedstock that is used to make other chemicals.

Because the use of benzene as an ingredient in consumer products has declined significantly, and since other chemicals have become the standard of the industries that produce such consumer products, no significant environmental effect is expected to result from the ban on benzene as an intentional ingredient. In addition, no significant environmental effect is expected as a result of limiting the level of benzene contamination in products. The level that is proposed appears to be a typical level of contamination in common petroleum distillates, the class of products that is likely to contain benzene as a contaminant.

All of the substitutes for benzene are acutely toxic to humans when inhaled. However, benzene alone has been shown to cause chronic blood disorders, including leukemia, in persons who are exposed to it. While questions have been raised concerning the chronic toxicity of methylene chloride, methylene chloride has long been the standard ingredient in paint strippers. Therefore, a ban on benzene will not substantially increase an already significant use of methylene chloride in these products. The ban, if finalized, is expected to have a beneficial effect on the health of consumers.

The method of disposal of rubber cement and paint strippers that do not contain benzene is the same as for those that do. In nearly all cases of use, the active ingredient in the product is volatile and evaporates into the air. Following use, the container and its residue are disposed of along with other household refuse. The ban is, therefore, expected to have no significant impact on land fills or other disposal media, or on air or water quality.

The environmental assessment is available for review in the Office ofd the Secretary of the Commission.

ANTICIPATED EFFECTIVE DATES

The Commission has preliminarily assessed the possible effects on the relevant industries of banning consumer products, except gasoline and solvents and reagents for laboratory use, containing benzene as an intentional ingredient or as a contaminant at a level of 0.1 percent or greater by volume. The Commission notes that the few firms currently using benzene as an intentional ingredient will have to reformulate their products, test the new formulations, and acquire different chemical supplies. Based on discussion with the affected companies and experience with other industries with similar problems, the Commission believes that since few reformulation problems should be presented, 60 days is a sufficient period of time for these firms to bring their products into compliance. Therefore, the Commission proposes that consumer products containing intentionally added benzene manufactured or imported 60 or more days after publication by the Commission of a final rule be declared banned hazardous products.

Alternatively, because of the severe nature of the hazard associated with consumer products containing high levels of benzene, the Commission is also proposing a shorter effective date with retrospective application to all products still in the channels of commerce containing intentionally added benzene. The Commission believes it may be necessary to halt all distribution in commerce of products containing intentionally added benzene shortly after the final ban is published so that consumers will not be able to purchase them and thus, continue to be exposed to benzene while supplies are exhausted. Shortening an effective date to less than 30 days from the date of publication of a final rule is authorized by section 553(d)(3) of the Administrative Procedure Act if the Commission so provides for good cause found and published with the rule.

Therefore, the Commission may make the final ban applicable to consumer products containing intentionally added benzene which are initially introduced into commerce 15 days after publication of a final ban. In addition under this option, all other consumer products containing intentionally added benzene, no matter when manufactured or initially introduced into commerce, would be banned 30 days after the publication of a final ban. This means that 15 days after publication of a final rule, manufacturers would be prohibited from shipping the product to distributors, retailers, consumers, or to others. Further, 30 days after publication of a final rule all manufacturing, selling, offering for sale or distributing in commerce of the described products would be prohibited, no matter when initially introduced into commerce.

The Commission does not believe that this alternative proposed effective date will have a major economic impact because so few firms are currently making products containing intentionally added benzene. The Commission staff is continuing to investigate the potential economic and environmental effects associated with the selection of this alternative date. The Commission is particularly interested in public comment on both proposed effective dates.

As to firms that manufacture products containing benzene as a contaminant at a level that is higher than the proposed limit, the Commission notes that these firms must consider alternative chemicals or new sources of supply and may also have to work down or otherwise dispose of inventories of contaminated ingredients. While little information exists on the difficulties that various firms may actually have in dealing with these problems, the Commission staff estimates that 120 days would be a reasonable time period for firms to bring their products into compliance. On this basis, the Commission proposes that consumer products containing benzene as an impurity at levels of 0.1 percent or greater manufactured or imported 120 days or more after publication of a final rule be banned.

The Commission has decided that the ban on benzene as a contaminant in products need only apply to products manufactured or imported after the effective date, not to those held in inventory after the effective date. The Commission notes that these products contain significantly smaller amounts of benzene than those for which the earlier effective date is proposed. The Commission also believes that banning products containing benzene as an impurity manufactured or imported prior to the effective date of this Part 1307 might result in a chaotic situation since the products were manufactured prior to a significant amount of testing; and therefore, extensive testing would be needed to determine

/hich products contain 0.1 percent or ıore of benzene.

SECTION 8—FINDINGS

Section 8 of the CPSA requires that, ı order to propose a ban, the Commis-on must find that a consumer prod-ct is being or will be distributed in ›mmerce, that it presents an unrea-›nable risk of injury and that no fea-ble consumer product safety stand-rd under the CPSA would adequately rotect the public from that unreason-ble risk.

The Commission finds that the prod-cts banned by the proposal are being ıd will be distributed in commerce.

A. UNREASONABLE RISK OF INJURY

In determining whether a specific sk of injury is "unreasonable", the ommission generally balances the robability that the risk will result in arm and the gravity of the harm gainst a rule's effect on the product's tility, cost, and availability to the ›nsumer. In this instance, the Com-ıission notes that the risk of injury ·om benzene-containing products is reat and includes leukemia as well as ther blood disorders. In addition, the ommission staff risk assessment sug-ests an increased lifetime risk of eath from myelogenous and monocy-ic leukemia of between 15.2 percent ınd 37.1 percent due to the use of ben-zene-containing paint strippers for 5 hours a day, ten times in a lifetime.

The Commission has considered the effect on the cost, utility, and avail-ability of benzene-containing products and it is noted that this rule would eliminate the few such consumer prod-ucts, except gasoline and laboratory benzene, currently on the market. However, the Commission also notes, as is discussed under Economic Consid-erations, that there are readily availa-ble substitute products at approxi-mately the same cost which will yield a slightly less effective product.

After considering the nature and degree of the hazard from benzene-containing products and the availabil-ıty of substitutes, the Commission con-cludes that the risk of injury clearly outweighs the effects of the proposed rule on the cost, utility, and availabil-ity of the products, and finds that ben-zene-containing products present an unreasonable risk of injury to the public.

B. FEASIBILITY OF A STANDARD

The Commission has considered all ·vailable information concerning the isk of injury associated with consum-r products containing benzene as an ıtentional ingredient and as a con-ıminant and believes that the risk of ıjury is inherent in the products as ›ng as they contain benzene.

The Commission believes that it is ıot possible to manufacture safe rubber cements or paint removers con-taining benzene because a safe level of exposure to benzene is not known. Furthermore, a standard such as OSHA's which sets a permissible air concentration level for benzene and re-quires protective clothing and equip-ment is not feasible for the consumer due to the cost of equipment and the knowledge required for its use.

In addition, except for laboratory use, the Commission notes that it does not believe that any required labeling for benzene-containing consumer products no matter how explicit and graphic would be adequate to address the risk of injury. (Current regula-tions under the FHSA at 16 CFR § 1500.14 (a)(3) and (b)(3) require cau-tionary labeling for products which contain 5 percent or more by weight of benzene including the words "danger", "vapor harmful", and "poison".) Since there is no known safe level of expo-sure to a carcinogen, the Commission believes that exposure to benzene must be reduced to the lowest possible level. The cautionary labeling, which would be necessary to approach that level, such as suggesting the use of a laboratory ventilation hood or the wearing of an adequate facemask when using benzene products, is im-practical for the average consumer, outside of a supervised laboratory situ-ation. The Commission notes in this regard that the type of respirator (chemical cartridge respirator) that would mitigate the effects of benzene-containing products is not generally available to households and even if it was, the specialized maintenance of this device would be burdensome to consumers. In addition, there is the possibility that any recommended pro-tective measures may not be followed in practice or may be followed by the user but not by bystanders or visitors.

Therefore, the Commission con-cludes that a standard, including a la-beling standard, for consumer prod-ucts containing benzene as an inten-tional ingredient or as a contaminant is not feasible at this time and that only banning these products can ade-quately protect the public from the unreasonable risk of injury associated with them.

EXTENSION OF TIME TO PUBLISH FINAL RULE

Section 9(a)(2) of the CPSA (15 U.S.C. 2058(a)(2)) requires the Com-mission in declaring a product to be a "banned hazardous product" to pub-lish a notice of proposed rulemaking in the FEDERAL REGISTER and to pro-vide interested persons with an oppor-tunity to participate in the rulemaking through submission of written data, views, or arguments. In addition to these written comments, interested persons must also be given an opportu-nity for the oral presentation of data, views, or arguments.

Section 9(a)(1) of the CPSA provides that within 60 days after publication of a proposed rule, the Commission shall promulgate a final rule or with-draw the proposal. The Commission may extend the 60 day period for good cause and must publish its reasons for extension in the FEDERAL REGISTER.

In the case of benzene-containing consumer products, the Commission has expressed a particular interest in obtaining public comment on the pro-posed contaminant level, on the issue of toxicity of substitutes, on the pro-posed effective dates, and on the var-ious health and economic findings re-quired by section 9(c) of the CPSA (see below). to afford an ample oppor-tunity for obtaining such comment, the Commission has decided that, in addition to holding a public meeting in Washington, D.C., the comment period, in which the public is invited to submit written comments on the proposed ban, is to be longer than the 30 day period usually provided. Writ-ten comments may be submitted until June 30, 1978.

It is anticipated that becuase of the extended comment period and the need for careful analysis of the pub-lic's oral and written views, more time will be required than the 60 day period provided in section 9(a) of the CPSA between publication of a proposal and publication of any final rule.

Therefore, the Commission has de-cided that this 60 day period should be extended. In order to conserve the re-sources that would be needed to issue such an extension of time during the comment and evaluation period, the Commission announces in this propos-al that good cause is found to extend for 90 days, until October 16, 1978, the time in which the Commission must either issue a final rule concerning benzene-containing consumer products or withdraw the proposal to ban. This period may be further extended for good cause and announced in the FED-ERAL REGISTER.

CONCLUSION AND PROPOSAL

Based on the foregoing information, the Commission proposes to declare that all comsumer products, except gasoline and solvents or reagents for laboratory use, containing intentional-ly added benzene or containing ben-zene as a contaminant at levels of 0.1 percent or greater are banned hazard-ous products.

Accordingly, pursuant to provisions of the CPSA (sections 8, 9, and 30(d), 86 Stat. 1215-17, 1231, as amended 90 Stat. 506, 510; 15 U.S.C. 2057, 2058, 2079(d)), the commission proposes that Title 16, Chapter II, be amended by adding to Subchapter B the follow-ing new Part 1307:

Part 1307—Ban on Consumer Products Containing Benzene as an Intentional Ingredient or as Contaminant

Sec.

1307.1 Scope and application.
1307.2 Purpose.

Sec.
1307.3 Definitions.
1307.4 Exemptions.
1307.5 Consumer products containing benzene as an intentional ingredient as banned hazardous products.
1307.6 Consumer products containing benzene as a contaminant as banned hazardous products.

AUTHORITY: Secs. 8, 9, 30(d), Pub. L. 89-573, as amended, Pub. L. 94-284, 86 Stat. 1215-17, 1231 as amended 90 Stat. 506, 510 (15 U.S.C. 2057, 2058, 2079(d)).

§ Scope and application.

(a) In this Part 1307 the Consumer Product Safety Commission declares that all consumer products, except gasoline and solvents and reagents for laboratory use, containing intentionally added benzene are banned hazardous products under sections 8 and 9 of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2057 and 2058). The Commission also declares that consumer products, except gasoline and solvents and reagents for laboratory use, containing benzene as a contaminant at levels of 0.1 percent or greater by volume are banned hazardous products under sections 8 and 9. This Part applies to products which are customarily produced or distributed for sale to or for the personal use, consumption, or enjoyment of consumers in or around a permanent or temporary household or residence, a school, in recreation or otherwise.

(b) The Commission has found (1) that the products described in subsection (a) are being or will be distributed in commerce, (2) that they present an unreasonable risk of injury, and (3) that no feasible consumer product safety standard under the CPSA would adequately protect the public from the unreasonable risk of injury associated with these products.

§ 1307.2 Purpose.

The purpose of this rule is to ban consumer products containing benzene as an intentional ingredient or as a contaminant. These products present an unreasonable risk of injury because exposure to the fumes increases the risk of developing blood disorders, chromosomal abnormalities, and leukemia.

§ 1307.3 Definitions.

(a) The definitions in section 3 of the Consumer Product Safety Act (15 U.S.C. 1052) apply to this Part 1307.

(b) "Benzene as an intentional ingredient" is benzene which is added deliberately to a product to impart specific characteristics.

(c) "Benzene as a contaminant" is any benzene appearing in a final product, which benzene is not an intentional ingredient. This includes any benzene which appears as a component of or impurity in a raw material used in the final product.

(d) "Imported" is the first entry of a product within a U.S. port of entry.

§ 1307.4 Exemptions.

The following categories of products are exempt from the ban established by this Part 1307:

(a) Gasoline.

(b) Benzene manufactured and distributed for use in laboratories as a solvent or reagent.

§ 1307.5 Consumer products containing benzene as an intentional ingredient as banned hazardous products.

On the basis that consumer products containing benzene as an intentional ingredient present the hazards of blood disorders, chromosomal abnormalities, and leukemia to the public, such products, except gasoline and solvents or reagents for laboratory use, manufactured or imported after the date which is 59 days after publication of the final rule in the FEDERAL REGISTER are banned hazardous products. Alternatively, such products, except gasoline and solvents or reagents for laboratory use, which are initially introduced into commerce 15 or more days after publication of a final ban are banned hazardous products. In addition, all other consumer products containing benzene as an intentional ingredient, no matter when manufactured or initially introduced into commerce, are banned hazardous products 30 days after the publication of a final ban.

§ 1307.6 Consumer products containing benzene as a contaminant as banned hazardous products.

On the basis that consumer products containing benzene as a contaminant at levels of 0.1 percent or greater by volume present the hazards of blood disorders, chromosomal abnormalities, and leukemia to the public, such products, except gasoline and solvents and reagents for laboratory use, manufactured or imported after the date which is 119 days after the publication of the final rule in the FEDERAL REGISTER, are banned hazardous products.

WRITTEN COMMENTS

Interested persons are invited to submit written comments before the close of business on June 30, 1978. Comments may be accompanied by written data, views, and arguments and should be submitted preferably in five copies, addressed to Secretary, Consumer Product Safety Commission, Washington, D.C. 20207. Received comments and other related material may be seen in the Office of the Secretary, Third Floor, 1111 18th Street NW., Washington, D.C., during working hours Monday through Friday.

ORAL PRESENTATIONS

Interested persons will be afforded an opportunity to make an oral presentation of data, views, or arguments in addition to the opportunity to make written comments, or any aspect of the proposed ban on June 14, 1978. The proceedings for the oral presentation will be held at 9:30 a.m. at the Commission's hearing room at 1111 18 Street NW., Washington, D.C. The procedural regulations for oral presentation, 16 CFR Part 1109, promulgated October 14, 1975 (40 FR 49122), shall govern this proceeding.

All persons wishing to make an oral presentation should notify Richard Danca of the Office of the Secretary, 202-634-7700, no later than close of business June 7, 1978, for scheduling purposes. A summary or outline of each oral presentation and an estimate of the length of time it will require should be filed with the Office of the Secretary at least business days prior to the oral presentation.

SECTION 9 FINDINGS

Section 9(c) of the CPSA (15 U.S.C. 2058(c)) requires the Commission, prior to promulgating a consumer product safety rule, to consider and make certain findings for inclusion on that rule. The Commission has discussed information relevant to these findings in the preamble of this document. However, in order to aid the Commission in obtaining the most complete and accurate information before making these findings, the Commission is particularly interested in receiving, either by written comment or through the oral presentation, additional data, views, and arguments as to the following:

1. The degree and nature of the risk of injury the rule is designed to eliminate or reduce;

2. The approximate number of consumer products, or types of classes thereof, subject to the rule;

3. The need of the public for consumer products subject to such rule and the probable effect of such rule upon the utility, cost, or availability of such products to meet that need;

4. Any means of achieving the objective of the rule while minimizing adverse effects on competition or disruption or dislocation of manufacturing and other commercial practices consistent with the public health and safety;

5. The necessity of the rule to eliminate or reduce the unreasonable risk of injury associated with the consumer products subject to the rule;

6. Whether the rule is in the public interest;

7. The feasibility of a consumer product safety standard under the CPSA to protect the public adequately from the unreasonable risk of injury associated with the products which are the subject of this proposed ban;

8. The potential environmental effects of the rule;

9. Available toxicity data regarding acute and chronic effects of all potential substitutes for benzene in products;

10. The appropriateness of the proposed contamination level for benzene in consumer products and the cost of achieving this level or any other suggested level;

11. The proposed effective dates;

12. Any adverse effects that this proposed ban will have on elderly and handicapped persons; and

13. The need and appropriateness of the gasoline and laboratory benzene exemptions.

Dated: May 15, 1978.

SADYE E. DUNN,
Acting Secretary, Consumer Product Safety Commission.

APPENDIX

Benzene is a clear, colorless, non-corrosive, flammable liquid with a rather pleasant odor. Benzene has a low boiling point and a high vapor pressure which causes it to evaporate rapidly, giving off vapors nearly three times heavier than air. These properties are responsible for the fact that considerable concentrations of benzene will rapidly appear in the air when benzene is used in open systems.

In the U.S. approximately 11 billion pounds of benzene were produced in 1976 (*1*). About 86 percent of this benzene was used as an intermediate in the production of other organic chemicals. The remainder was used in the manufacture of detergents, pesticides, solvents and paint removers. Benzene is also present in motor fuels and raises the octane levels of gasoline: In United States gasoline, the average benzene content is roughly one percent but ranges from 0.2–4.3 percent (*2*).

In consumer products benzene may be present in such products as rubber cements, paints, varnishes, stain removers and adhesives. Benzene has been recognized as being a toxic substance for over 75 years. It causes both acute and chronic effects. Considerable evidence has been collected that the chronic toxic effects of benzene include leukemia, bone marrow suppression and chromosomal abnormalities. Since benzene is implicated as a carcinogen and that for any carcinogen there is no zero risk level for a given population, exposure to this compound must be limited.

A. TOXIC EFFECTS OF BENZENE

1. *Metabolism.* The major route of entry of benzene into the body is via inhalation. Benzene rapidly reaches equilibrium with the air in the lungs and rapidly diffuses into the blood (*3*). In experiments with rats, the concentration of benzene in blood was shown to parallel the concentration in the inspired air (*4*). Benzene is retained in the body for many hours after exposure is terminated, and elimination through the lungs accounts for only 12 percent of the elimination during the first six hours after exposure.

Exposure to benzene can also be by direct contact, although benzene absorption through non-damaged human skin is not very great (*5–7*). When direct contact occurs, obviously there usually is inhalation of the vapors.

Benzene is highly lipid soluble and accumulates in various body organs in proportion to their fat content. It accumulates particularly in fat, bone marrow and the central nervous system. Elimination of benzene from the body takes place by respiration and by metabolism. Elimination of unchanged benzene from respiration ranges from 12–50 percent of the total amount absorbed, while very small amounts are excreted in the urine (*8*).

Benzene appears to be metabolized mainly by the liver. The first step appears to be a reaction that forms benzene oxide. This intermediate has been suggested as a possible candidate for the bone marrow toxicity of benzene (*9*). The principal metabolites are the phenols, formed by enzymatic hydroxylation. The phenols are then further processed by sulfation or glucuronization to give the conjugated end products catechol, hydroquinone and phenyl-mercapturic acid which are also found in the urine in small amounts as well as phenol (*7*). It has been reported that both catechol and hydroquinone depress bone marrow activity, and therefore are also candidates for the chronic toxic effects of benzene (*8*).

2. *Acute toxicity.* Benzene concentrations of about 20,000 ppm are fatal within minutes, with death occurring from acute circulatory failure or coma. The symptoms of acute toxicity may include convulsions, muscle tremors, salivation, nystagmus and phenomena of very intense asphyxiation due to paralysis of the medullary respiratory center (*9*). Sub-lethal exposures produce nervious excitation, euphoria, headache, nausea and vomiting, weakness and abdominal pains. This will be followed by a period of depression which can lead to cardiovascular collapse and unconsciousness. Exposures of about 250–500 ppm gives signs and symptoms of mild poisoning, such as dizziness, drowsiness, headache and nausea. These usually disappear rapidly after removal from exposure.

Direct skin contact with liquid benzene also may cause redness and blistering. Chronic skin dryness and scaling have also been found.

3. *Chronic toxicity in man.* The major site of benzene's chronic toxicity is on the bone marrow, the blood-forming organ. In this section representative studies from the medical literature will be cited, demonstrating the diversity and seriousness of benzene exposure on hematopoiesis. This is not meant to be an all-inclusive review of this subject, rather an indication of the diseases that have been implicated to occur with chronic benzene exposure.

The emphasis in this section is primarily on studies that have evaluated substantial numbers of occupationally exposed people, particularly where measurement of dose has been attempted.

In most reported cases of benzene hematoxicity, exposure has been in a working situation where benzene was used as a solvent or manufactured as a product. One problem is that exposure usually occurs to a mixture of volatile compounds, rather than to benzene alone. Despite this, the overwhelming evidence points to an association of hematopoietic disease with benzene. The evidence includes the fact that benzene has been the common demoninator in various settings where exposure to other compounds has varied extensively; there are good epidemiological studies showing that outbreaks of hematoxicity followed the introduction of benzene to the workplace and responded to replacement of benzene with other solvents; and that bone marrow toxicity occurs in animals exposed only to benzene.

It is possible that compounds inhaled along with benzene alter the expression of hematotoxicity. Both other aromatic hydrocarbons, as well as chemically unrelated chemicals could conceivably modify benzene metabolism in man.

(a) *Pancytopenia and aplastic anemia.* Pancytopenia refers to a decrease in all of the formed elements of the blood, red blood cells (erythrocytes), white blood cells (leukocytes), and platelets (thrombocytes). In benzene exposures these elements decrease primarily due to a decrease in production. The term aplastic anemia is often used to describe benzene toxicity. However, this term classically denotes a condition in which pancytopenia is accompanied by a marked decrease in the number of hematopoietic precursor cells within the bone marrow (hypoplasia). In benzene toxicity manifested by pancytopenia, the bone marrow studies have varied, with hypoplasia (*11–13*), normal cellularity (*11, 14*), and even hyperplasia (*11, 14*), being found. For the purpose of this discussion, pancytopenia will be discussed as a single entity, regardless of the bone marrow findings (if performed).

Among the earliest investigations of pancytopenia in benzene exposure were those of workers in rotogravure printing plants (*15–17*). In the studies, the workers had been exposed to benzene for a period of 3–5 years. The benzene contents of the ink solvents and thinners were between 10–80 percent. The air concentrations were analyzed and ranged from 11–1,060 ppm with a median level of 132 ppm. The workers complained of fatigue, lethargy, dizziness, headache, shortness of breath and dryness of the mucuous membranes. Hematological studies were performed in 332 exposed male workers and 81 controls. Sixty-five of these people had some degree of hematological toxicity while 23 were severely affected. Six of these people were hospitalized; the remainder continued working and, following discontinuation of benzene use, recovered (*17*). These investigators found anemia, macrocytosis (large red cells) and thrombocytopenia (low platelet count). They rarely observed neutropenia (low granulocytic white cell count), but a decrease in lymphocytes appeared more commonly. They also found in a few cases prolongation of the bleeding or clotting times, an increase in capillary fragility and an increase in serum bilirubin and reticulocytes.

Wilson (*10*) in 1942 reported a study of 1,104 workers in an American rubber factory exposed to a maximum level of 500 ppm benzene, with an average of approximately 100 ppm. Of these, 83 were found to have mild hematological abnormalities and 25 more had severe pancytopenia. Nine of these 25 were hospitalized and 3 died as a result of the pancytopenia.

A study in England of 200 women exposed to benzene in 13 aircraft factories in England was reported in 1944 (*18*). This was in the manufacture of rubber and the women had been exposed in solvents containing 5–20 percent aromatic hydrocarbons including benzene. In this study, neutropenia was the most consistent indicator of benzene toxicity. No significant differences in red cells or lymphocyte counts was found.

In a rubber raincoat factory in Sweden (*19*), 189 people were studied. The benzene

levels were measured and found to be 137-218 ppm. Hematological toxicity was found in 60 people. After 16 months of no further benzene exposure, 46 had recovered, 12 still had significant abnormalities and 2 had died. Prominent in this group was the finding of thrombocytopenia.

In an Australian air force workshop study (*20*) of 87 exposed people there was one case of fatal pancytopenia. The benzene peak concentration ranged between 10-1,400 ppm and in most areas the benzene concentration was well above 100 ppm. The average concentration was 10-35 ppm. The solvents contained up to 53 percent benzene.

In 1961 (*21*) a study was performed in rubber coating plants where petroleum naphtha containing 1.5-9.3 percent benzene was in use. Benzene levels were usually less than 25 ppm but did go as high as 125 ppm. In one plant, 5 of 32 men had anemia; in a second plant, 1 of 9 was anemic and in a third plant, all workers studied were normal.

In the Soviet Union, Doskin (*22*) reported an evaluation of 365 workers exposed to benzene for 1-3 years. The benzene levels ranged between 10-40 ppm. It was reported that 40 percent of the workers had hematological changes during the first year. The most common early sign was thrombocytopenia, followed by anemia. An initial increase in white blood cell count was followed in some cases by leukopenia.

In another study, Kozlova and Volkova (*23*) studied 252 workers exposed to benzene over a 5-year period. Initially the benzene concentrations ranged from 47-310 ppm, but by the end of the 5 years had decreased to 25-47 ppm. The workers were classified into 3 groups according to exposure levels, the lowest being 24-39 ppm. In all 3 groups there was a decrease in all cell counts, with the most severe cases being in the highest exposure group. These investigators found leukopenia (mainly neutropenia) and thrombocytopenia as the most prominent early findings. Red cell changes were noted as a later phenomenon.

Savilakti et al. (*24, 25*) evaluated people exposed to benzene in a shoe factory in Finland. In this group of 147 persons, 107 were found to have abnormal blood counts, the most common being thrombocytopenia. Ten people required hospitalization and one died of severe pancytopenia. In 1964 (9 years after cessation of benzene exposure) 125 of these workers were re-examined. Combined assessment of the cell counts revealed the difference between the exposed and the controls was significant for males, but not for females. There was a greater tendency towards recovery of leukocytes rather than erythrocytes or platelets.

Girard and colleagues in France (*26, 27*) questioned all of their patients with hematological diseases concerning benzene exposure and reported the percentage of individuals with a given hematological disease and known exposure to benzene. Pancytopenia had the highest association. Of all of their patients with the diagnosis of aplastic anemia, 20.8 percent had exposure to benzene or toluene. In contrast, only 4 percent of controls (non-hematological disease) had exposure to these agents.

Aksoy et al. (*28*) in Turkey examined 217 apparently healthy men who had worked for 3 months to 17 years in shoe factories using an adhesive containing benzene. These workers were exposed to 30-210 ppm benzene. In 51 of these people some form of hematological abnormality was found. Anemia was the most common finding, but since it was correctable by iron, it was not ascribed to benzene. However, the volume of the cells (mean corpuscular volume) was high normal to slightly elevated range which is unusual for iron deficiency and is more consistent with what has been seen with benzene (macrocytosis). Leukopenia with or without thrombocytopenia was the most common finding attributed to benzene. Pancytopenia was seen in 6 people.

In 1977 Aksoy et al. (*29*) reported they had previously studied 46 patients with aplastic anemia who had been exposed to benzene. Of these patients 14 had died of aplastic anemia, 5 had developed acute leukemia, 1 had developed myeloid metaplasia, 22 were in complete remission, 2 were still under treatment and 2 were lost to follow up. All of these people had been exposed to adhesives containing 9-88 percent benzene and exposure was generally in small shops with poor ventilation. Where measured, the benzene concentration was 150-650 ppm.

In addition to this data in humans there is strong support from the medical literature, using animal models, that benzene causes pancytopenia. The route of administration to animals has been both by inhalation and injection (usually subcutaneously).

In the inhalation studies, Weiskatten et al. (*30*) produced leukopenia, slight anemia and hemorrhages in rabbits exposed to approximately 240 ppm benzene for 10 hours a day. The effects were observed within 2 weeks of exposure. This study found that "small mononuclear white cells" (probably lymphocytes) were the most depressed.

Svirbely et al. (*31*) studied rats and dogs exposed to 1000 ppm benzene 5 days a week, 7 hours a day for 28 weeks. The rats had intermittent leukopenia and lymphocytopenia, while the dogs had lymphocytopenia throughout the study.

Li et al, (*32*) found varying results in dogs exposed to 600 ppm benzene for 42 hours per week over periods of time dependent on their response to benzene. Some animals (least affected) could be exposed to up to one year, while others became moribund in 5-6 weeks. These investigators monitored leukocytes and platelets and found a decrease in the number of both. Protein deficient diets produced greater reductions, which were exacerbated by high fat diets.

Wolff et al. (*6*) exposed rats, guinea pigs and rabbits to benzene for 7 hours periods for various numbers of days. They stated that they saw leukipenia at levels as low as 80 ppm.

Deichmann et al. (*4*) exposed rats to benzene at various doses for 5 hours per day, 4 days a week. They report leukopenia at a benzene concentration as low as 44 ppm for 2-8 weeks. They did not observe leukopenia at concentrations of 31, 29 or 15 ppm. Female animals were more sensitive than males.

Nau et al. (*33*) found leukopenia in rats with exposure to 1000, 200, and 50 ppm benzene. The reported toxicity occurred more rapidly with the higher doses, but did occur at 50 ppm after long exposures.

Ikeda (*34*) exposed rats to 1000 ppm benzene for 7 hours a day, 5 days a week for 60 days. They noted leukopenia which decreased in the following order: adult males, young males, adult females, young females.

Baje et al. (*35*) noted leukopenia in rats exposed to 400 ppm benzene 7 hours a day for 13 weeks.

Benzene-induced hematological toxicity in animals has also been produced by administering benzene by injection. Santession (*36*) in 1897 was the first person to suggest benzene as a cause of hemorrhagic phenomena by subcutaneous injection of rabbits. Selling (*37*) was able to demonstrate severe leukopenia in rabbits by injection of 1 ml/kg benzene (as a 50% solution in olive oil) per day in 4-9 days. In Selling's study complete aplasia of the bone marrow was first noted.

Gerarde (*38*) performed similar experiments in rats treated daily for 2 weeks with 1 ml/kg of benzene (50 percent solution in olive oil). Leukopenia was noted during this time which was reversible.

Latta and Davies (*39*) gave rats 50 percent benzene in olive oil at 2, 3, and 4 ml/kg daily for up to 60 days. They noted first a temporary stimulation of white cell production. After this the leukocyte count fell with lymphocyte production being more severely impaired. With the high dose they found disappearance of bone marrow myelocytes after 24 days and complete aplasia after 60 days.

Speck et al (*11-13*) gave benzene to rabbits at doses of 0.2 and 0.3 ml/kg per day and produced severe leukopenia within 1-9 weeks. They also noted a decrease in red cells, hemoglobin, reticulocytes and platelets. Pancytopenia was a common finding. The bone marrows from the pancytopenic animals were interpreted as very hypoplastic (21 percent), hypoplastic (32 percent), normal (26 percent) and hypercellular (21 percent).

Lee et al. (*40*) treated mice with benzene in corn oil at 400 mg/kg and 2200 mg/kg as single doses and demonstrated that benzene depresses the incorporation of radioactive iron into circulating red cells. Their results are compatible with an effect of benzene at the early bone marrow precursors of red cells.

Summary of Benzene-Associated Pancytopenia

Benzene exposure has been clearly demonstrated to produce hematotoxicity in man. The most commonly reported effect is a decrease in one or more of the formed elements of the blood. In more severe cases this will take the form of pancytopenia, including in some cases an aplastic bone marrow. The evidence that benzene is causally related to pancytopenia includes studies showing that outbreaks of pancytopenia throughout the world have followed the introduction of benzene to the workplace and that these outbreaks will stop when benzene is substituted for by other solvents.

As confirmatory evidence, it is possible to induce similar hematological effects in animals treated with benzene. At the present time it is not possible to establish a definitive, safe dose or time exposure, nor is it possible to state what (if any) age, sex, social or ethnic groups are more or less susceptible to benzene toxicity.

(*b*) *Leukemia:* Leukemia is a term for a group of diseases with an abnormal proliferation of white blood cells or their precursors in the peripheral blood and bone marrow, often with the appearance of abnormal immature white cell precursors in the blood. Leukemia is considered to be a malignant neoplasm. Evidence in man industrially exposed to benzene has strongly implied that benzene is directly related to the development of acute myeloblastic leukemia and its variants such as erythroleukemia and acute myelomonocytic leukemia. There have been numerous case reports in the medical literature suggesting that there is this association. However, in this report

the more recent larger epidemiological studies will be reviewed.

In the past 10 years, Aksoy and his coworkers in Turkey have performed careful studies strongly suggesting that benzene exposure leads to acute leukemia (*29, 41-44*). Their evidence includes reports of workers with aplastic anemia which progressed through a "pre-leukemic" phase to a typical acute myeloblastic leukemia or erythroleukemia. The outbreak of leukemia occurred in shoemakers when benzene use in an adhesive was introduced. Leukemia cases subsided after benzene use was discontinued.

Aksoy et al. (*27, 41, 42*) observed 26 petients with acute leukemia in this group of shoemakers. The benzene concentration in air reached a maximum of 210–650 ppm when the benzene-containing adhesives were in use. The cases included 14 cases of acute myeloblastic leukemia, 3 of acute lymphoblastic leukemia, and 1 each of acute monocytic and promyelocytic leukemia. These investigators had evaluated 28,500 shoe workers in Istanbul and calculated a leukemia risk of 13 per 100,000 in this group (*29*). This is compared to an incidence of leukemia in Turkey of 2.5–3.0 per 100,000. In order to be extremely careful in these studies, Askoy et al compared their results to the incidence of leukemia in developed nations (6 per 100,000). The incidence of leukemia in shoeworkers in Turkey was statistically higher ($p < 0.02$) than this number. These studies, therefore, if anything, underestimate the risk of leukemia on benzene exposure. Furthermore, these investigators did not age-adjust their findings, which also underestimates the risk of leukemia.

Recently, Aksoy (*29*) summarized his experiences with this group of patients. He reported that between 1967–1971 there was a notable incidence of pancytopenia followed by a peak incidence of leukemia between 1971–1973. Since 1969 there was a gradual decline in the use of benzene in this occupation, and there was a decline in leukemia after 1973, with no cases in 1976. Aksoy also reported that he was able to identify pancytopenia in 27.5 percent of the cases 6 months to 6 years before the onset of acute leukemia. The pancytopenia appeared to be recovering before the onset of acute leukemia. Aksoy (*29*) has stated that he is of the opinion that pancytopenia is not a necessary precursor to acute leukemia.

Another series of studies have been reported by Vigliani and his colleagues in Northern Italy. In recent reviews Vigliani (*46*) and Vigliani and Forni (*47*) summarized their experiences from 1942–1975. In Pavia they reported 135 patients with benzene hematotoxicity of which 13 died of acute myeloblastic leukemia (or its variants) and 3 of aplastic anemia. In Pavia the patients were workers in the shoe industry and were exposed to adhesives containing benzene. Benzene concentrations ranged from 25–600 ppm, but usually were 200–500 ppm. In Milan they saw 66 cases of benzene hematotoxicity, of which 11 were cases of acute myeloblastic leukemia (or its variants). In addition to these 11 fatal cases of leukemia, 7 additional patients died of aplastic anemia. In Milan many of the patients were also in the shoe industry, but other occupational groups were also affected. They reported an outbreak of benzene hematotoxicity in the rotogravure industry which occurred after inks and solvents containing benzene were introduced to the workplace. Benzene concentrations in the air were 200–1500 ppm. Vigliani has reported that he knows of at least 150 cases of benzene-induced leukemia in Italy (*46*), and has also reported a 20-fold higher risk of acute leukemia in workers exposed to benzene (*48*).

In France, Girard and his colleagues (*49, 50*) have evaluated the frequency of a benzene exposure in 401 patients hospitalized with hematological diseases as compared to a control group of 124 patients hospitalized for nonhematological diseases. They found a statistically significant increase in benzene exposure in patients with aplastic anemia, acute leukemia, and chronic lymphocytic leukemia as compared to the control.

Recently in the USA, Infante et al. (*51*) have performed an epidemiological evaluation of benzene-exposed workers in two "Pliofilm" factories. These investigators report a five-fold increased risk of total leukemia and a 10-fold risk of acute myeloblastic leukemia (or its variant, myelomonocytic leukemia) in these workers. Since they were unable to determine the status of 25 percent of the workers and assumed that they were still living, if anything, this study would underestimate the risk of leukemia.

In contrast to the pancytopenic effects of benzene where there are abundant animal models, there has only been one study reported in 1932 (*52*) claiming that animals receiving benzene developed leukemia. The absence of controls and the uncertainty as to the strain of mice in this study makes it impossible to evaluate this study. While at least one study is presently being carried out in animals, it is too premature to draw conclusions from it (*53*).

Summary of Benzene-Associated Leukemia

Benzene exposure has been associated with an increased risk of development of acute myeloblastic leukemia and its variants. Most of this evidence has been collected from epidemiological studies of workers exposed to benzene, showing an increased number of cases of leukemia in these groups. Substitution of other solvents for benzene results in a decreased number of cases. There are no animal model systems at the present time. It is not yet possible to establish a safe dose or time exposure, nor is it possible to identify any group of people more susceptible to a leukemogenic effect of benzene. It is not known whether pancytopenia must precede leukemia.

(c) *Other abnormalities possibly associated with benzene exposure:* While pancytopenia and acute myeloblastic leukemia are the diseases most commonly considered with benzene exposure, there are other abnormalities which have been reported to occur.

Abnormalities in leukocyte function have been reported by a number of investigators. These changes could be important, as these cells are necessary to fight infection. Among the granulocyte abnormalities are a decrease in phagocytic function (*54*), a decrease in leukocyte alkaline phosphatase activity (*55, 56*), an alteration in osmotic fragility (*57*), a change in fluorescent characteristics of the nuclei (*58*) and the presence of the Pelger-Huet anomaly of the nuclei (*28, 59–62*). The Pelger-Huet anomaly, when it is acquired, has been associated with leukemias.

Lymphocytopenia has been reported to be a common finding in benzene toxicity (*28*) and Goldwater suggested that this is even more common than granulocytopenia (*16*). Other investigators have failed to observe this, and there are some reports of lymphocytosis (*62, 63*) in man. In animals, several groups have shown that benzene decreases lymphocytes and lymphoid tissues (*64, 66*). Snyder et al. (*65*) have recently shown that lymphocytopenia is a very early manifestation of toxicity in rats and mice exposed to 100–300 ppm benzene in the air. Further studies have suggested that there is an altered immune function in benzene-exposed people. Included in these have been findings of leukocyte agglutinins (*66*), decreased serum immunoglobinulins (*67, 68*) and complement levels (*69*) and antibodies against red cells, platelets, and leukocytes (*70*).

The "immune system" of the body includes lymphocytes, lymphoid tissue, immunoglobulins, and complement. This system is involved in protecting people from substances "foreign" to the body, such as infectious agents. It may also be involved in protection against development of malignancies. The noted effects of benzene on the immune system then raise the question of whether the association with leukemia might arise from an altered immune surveillance. Another possibility is that benzene somehow alters the bone marrow so that it is recognized as "foreign" and is attacked by the so-called "suppressor lymphocytes" which have recently been postulated to be involved in aplastic anemia in people (*71, 72*).

Still other leukocyte findings have been reported which include an increased number of another type of white cell, the ecosinophil (*24, 25*), as well as the monocyte, (*73*) with abnormal-appearing monocytes present.

Abnormal platelet function has also been reported in people exposed to benzene independent of a decrease in the number of platelets (*74–83*). Morphdogical abnormalities in peripheral blood platelets, as well as the bone marrow precursor, the megakaryocyte (*28, 80, 81, 82, 83*) have been reported. This also suggests that the coagulation factors are abnormal (*75, 79*).

Macrocytosis (large volume of the red cells) is the most frequently reported abnormality of the red cell associated with benzene toxicity (*16, 19, 28, 85–88*). Large red cell precursors (in the bone marrow, macroerythroblasts) have also been reported (*89, 90*). It has been suggested that macrocytosis is of prognostic importance and might be a warning signal of benzene hematotoxicity (*91, 92*).

Significant destruction of red cells (hemolysis) has also been reported in some people exposed to benzene (*84, 93–97*). There have also been a few cases of paroxysmal nocturnal hemoglobinuria (*98*), a rare hemolytic disorder due to an acquired defect of the red cell membrane. Of note is that this rare disorder has been associated with the development of both aplastic anemia and acute myeloblastic leukemia.

In recent years studies have been performed both in people exposed to benzene (*99, 100*) and in an in vitro rabbit reticulocyte system (*101–105*) showing that benzene affects heme synthesis by inhibiting the enzymatic system necessary to synthesize this compound. Heme is a porphyrin which is a portion of the hemoglobin molecule, but is also a part of many other proteins. It is found in all cells, but it is in greatest amounts in red cells and then liver cells. Recent work has shown that heme is necessary for maximal protein synthesis in most if not all cells (*106*). When heme synthesis in red cell precursors is decreased due to a deficiency of iron (iron deficiency anemia and the anemia of chronic disease) less protein (including hemoglobin) and less red

cells, will be produced. When the enzymes necessary to synthesize heme are inhibited protein synthesis and red cell production are also inhibited, but iron accumulates in the mitochondria of these cells. The accumulation of iron in the mitochondria gives a characteristic morphological picture and is termed a "sideroblastic anemia" (*107*). Of note is that "sideroblastic anemia" is a common presentation of a "preleukemia". It has been postulated (*108–109*) that a deficiency of heme in bone marrow pluripotential stem cells (precursors of all the marrow elements) could conceivably result in an inability to make protein and thus an inability to mature, divide, and make any of the formed cells of the blood.

While the association of benzene exposure and acute myeloblastic leukemia appears definite, the association with other types of leukemia and malignancies is still unclear. In France it has been noted that there is a relatively high incidence of chronic lymphocytic leukemia, often greater than that of acute myeloblastic leukemia in people exposed to benzene (*49, 50, 110*). Furthermore, three cases of chronic lymphocytic leukemia have been reported from the Soviet Union (*110*). In contrast, Aksoy in Turkey, Vigliani in Italy, and Infante in the United States have not reported this association. The reason for this difference is not yet clear.

There is also inconclusive evidence suggesting that benzene might be associated with other diseases, including acute lymphoblastic leukemia, lymphomas (*110–118*), chronic myelogenous leukemia, and myelofibrosis and myeloid metaplasia (*98, 119–121*).

Evidence has been presented that benzene causes chromosomal aberrations. Since most (if not all) carcinogens are mutagens, the observation that benzene causes chromosomal damage in man suggests that it is also a mutagen. Even though there is a rapid, convenient, accurate in vitro system ("The Ames Test") for mutagen testing (*122*), apparently benzene is too toxic for use in this test system (*123*). In any event the assessment of damage to mammalian chromosomes is probably much more directly relevant to estimation of human health hazards from a mutagen, than any in vitro test system.

Chromosomal damage can lead to cell death if it interferes with cell division (mitotic poison). If it does not interfere with cell division, the lesion is replicated and a mutation may result. Not all mutations will lead to malignant changes, but there is an increased likelihood of a malignancy when mutational events occur.

The mitotic poison effect of benzene has been well demonstrated. There is a decrease in DNA synthesis in in vitro cultures of human (*124, 125*) and animal cells after in vivo exposure to benzene (*11–13, 38, 126, 127*). A defect in RNA synthesis has also been reported (*11*) in the basophilic normoblast, but not in earlier red cell precursors. In these studies (*11*) it was implied that marrow from benzene-treated mice, injected into other mice (lethally irradiated), could still form colonies of bone marrow cells in the spleens. This is evidence that the pluripotential stem cells are not affected by benzene. These studies in animals used very high doses of benzene (0.2–0.3 ml/kg/day at least 3 times per week for 6–12 weeks). The studies were performed only after the animals had become pancytopenic. Of note is that toluene and xylene have not been toxic in these animal systems. Indeed, a recent report by Andrews et al. (*128*) has shown that toulene can protect against benzene-induced decreased incorporation of ^{59}Fe into red cells.

There have been several studies attempting to locate a nuclear lesion within cells of humans exposed to benzene. In healthy workers with a history of exposure to benzene, Tough and Court-Brown (*129–130*) have noted unstable chromosome damage such as breaks and gaps in cultured lymphocytes. Chromosomal abnormalities in people exposed to benzene without any clinical abnormalities have also have been noted in other studies (*55, 131, 132*). These changes were not noted in workers exposed to toluene (*133*).

In addition there have been numerous reports of chromosomal abnormalities in patients with hematological disease and a history of benzene exposure (*44, 133–136*). However, it is impossible to state whether or not these abnormalities are indeed due to benzene or a result of the underlying disease.

Summary. Benzene exposure has been implicated as causing abnormalities in the function of leukocytes, platelets, red cells, and the immune system. In addition, abnormalities in prophyrin and heme synthesis have been reported. It is possible, but not yet proven, that there is an increased risk of developing chronic leukemias and lymphomas. The abnormalities in chromosomes seen with benzene exposure are consistent with a mutagenic potential of this agent. However, these changes could result from the proven ability of benzene to act as a mitotic poison.

B. Conclusions

(1) Chronic benzene exposure has been shown to be associated with an increased risk of developing hematological disorders including pancytopenia, acute myeloblastic leukemia (and its variants, erythroleukemia and myelomonocytic leukemia), and chromosomal abnormalities. There is also evidence that benzene exposure causes abnormalities in poryphrin and heme synthesis and is associated with qualitative abnormalities in leukocytes, platelets, red cells, and the immune system. It is possible that there is also an increased risk of developing other leukemias, lymphomas, and hematological disorders.

(2) Neither the dose of benzene nor the time of exposure required to develop these complications is known. Neither is it known if benzene or a metabolite of benzene is the toxic agent. No particular groups have been definitively shown to be more susceptible to benzene.

(3) In consumer products there is no possible control as to the method of use, extent of exposure or length of exposure. An experiment to determine the amount of benzene exposure from a consumer product was recently performed by NIOSH (137). They used a paint remover purchased over the counter which was found by gas chromatography to contain 52 percent benzene by volume. To simulate a typical exposure, an end table was stripped in a home garage. Five samples of air were collected and found to contain 73–225 ppm benzene, with a mean of 130 ppm. These results were similar to that reported previously by Otterson measuring air concentrations of benzene in commercial furniture stripping factories. Therefore, the presence of benzene in consumer products constitutes a health hazard.

(4) There is no evidence at present that toluene or xylene which have been used as substitutes for benzene have the same chronic effects as benzene.

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[6355-01]

[16 CFR Part 1500]

PRODUCTS REQUIRING SPECIAL LABELING UNDER SECTION 3(b) OF THE FHSA; BENZENE

Proposed Amendment

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed amendment to rule.

SUMMARY: The Commission proposes to amend a regulation under the Federal Hazardous Substances Act (FHSA) which mandates special cautionary labeling for products containing 5 percent or more by weight of benzene. The proposed amendment provides that the FHSA regulation will not be applicable to consumer products, except gasoline, which are subject to a new regulation under the Consumer Product Safety Act (CPSA) banning benzene-containing consumer products, except gasoline and solvents and reagents for laboratory use. Elsewhere in this issue of the FEDERAL REGISTER the Commission proposes the new CPSA banning regulation.

DATES: Comments concerning this proposal must be received by June 30, 1978. It is expected that this amendment will become effective when any final CPSA ban concerning benzene is effective.

ADDRESS: Comments should be sent to Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207.

FOR FURTHER INFORMATION CONTACT:

Francine Shacter, Office of Program Management, Consumer Product Safety Commission, Washington, D.C. 20207, 301-492-6557.

SUPPLEMENTARY INFORMATION: In this issue of the FEDERAL REGISTER the Commission has proposed a rule (16 CFR Part 1307) under section 8 of the Consumer Product Safety Act (CPSA), declaring all consumer products, except gasoline and solvents or reagents for laboratory use, containing benzene as an intentional ingredient or as a contaminant at levels of 0.1 percent or greater to be banned hazardous products.

The Commission notes that there is currently in existence a labeling regulation under the Federal Hazardous Substances Act (FHSA) applicable to benzene which is intended to address, among other things, the risk of blood dyscrasias which may result from benzene inhalation. This regulation, at 16 CFR 1500.14 (a)(3) and (b)(3), requires that products containing 5 percent or more by weight of benzene must be specially labeled with the signal word "danger", the word "poison", the skull and crossbones symbol, and the statement of the hazard "vapor harmful." Products containing 10 percent or more by weight of benzene must bear the additional statement of hazard "harmful or fatal if swallowed" as well as the statement "If swallowed, do not induce vomiting. Call physician immediately."

The Commission now proposes to amend the FHSA regulation to indicate that it will not be applicable to products covered by the FHSA regulation that are also banned hazardous products under any final CPSA rule. Since proposed Part 1307 is applicable only to consumer products and specifically exempts gasoline, the FHSA labeling requirements are proposed to be retained for benzene-containing gasoline and for other hazardous substances containing benzene which are not consumer products—for example, certain automotive products which are excluded from Commission jurisdiction under the CPSA, but not under the FHSA, to the extent they are distributed for use in or around a household. In addition, the Commission concludes that any consumer products containing benzene that might not be covered by any final ban because of the date they are manufactured, imported or introduced into commerce, should continue to be subject to the FHSA labeling requirements.

Since the purpose of this proposed amendment is to eliminate the possibility of confusion concerning labeling products that are banned, it is proposed that the amendment be conditional upon Part 1307 being issued in final form and its continuing in full force and effect. If, at any time, any requirement of Part 1307 relating to products within the scope of § 1500.14 (a)(3) and (b)(3) is stayed, revoked, or set aside by judicial or other action, the amendment restricting the application of the FHSA labeling requirement is to be withdrawn, and a FEDERAL REGISTER notice will be issued reinstating full applicability of the FHSA regulation. It is proposed that this amendment will become effective at the same time any final CPSA ban concerning benzene is effective.

AMENDMENT

Accordingly, pursuant to provisions of the Federal Hazardous Substances Act (sec. 2(f)(1)(A), 3(b), 74 Stat. 372, 374, as amended 80 Stat. 1303-1304, 15 U.S.C. 1261(f)(1)(A), 1262(b); sec. 10(a), 74 Stat. 378, 15 U.S.C. 1269); and under authority vested in the Commission by the Consumer Product Safety Act (sec. 30(a), 86 Stat. 1231, 15 U.S.C. 2079(a)), the Commission proposes to amend 16 CFR 1500.14(b)(3) by adding a new subparagraph (iv) as follows:

§ 1500.14 Products requiring special labeling under section 3(b) of the act.

(a) * * *
(b) * * *
(1) * * *
(2) * * *
(3) *Benzene, toluene, xylene, petroleum distillates.*
(i) * * *
(ii) * * *
(iii) * * *

(iv) Since the Commission has issued a regulation under the Consumer Product Safety Act (CPSA) banning benzene-containing consumer products, except gasoline, covered by this labeling regulation (see 16 CFR Part 1307), subparagraph (i) of this subsection is inapplicable to consumer products containing benzene as an intentional ingredient, except gasoline, which are covered by Part 1307.

Subparagraph (i) continues to apply gasoline and other hazardous substances containing benzene, intended or packaged in a form suitable for use in the household, which are not "consumer products" as that term is defined in the CPSA.

This amendment is conditional upon Part 1307 continuing in full force and effect.

Dated: May 15, 1978.

SADYE E. DUNN,
Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 78-13664 Filed 5-18-78; 8:45 am]

[6355-01]

[16 CFR Part 1700]

SUBSTANCES REQUIRING SPECIAL PACKAGING; BENZENE

Proposed Amendment

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed amendment to rule.

SUMMARY: The Commission proposes to amend a regulation under the Poison Prevention Packaging Act of 1970 (PPPA), which requires child-resistant packaging for certain benzene-containing solvents for paint or other similar surface coating materials. The proposed amendment provides that the PPPA regulation will not be applicable to consumer products covered by the PPPA regulation which are subject to a new regulation under the Consumer Product Safety Act (CPSA) banning benzene-containing consumer products, except gasoline and solvents and reagents for laboratory use. Elsewhere in this issue of the FEDERAL REGISTER the Commission proposes the new CPSA regulation.

DATES: Comments concerning this proposal must be received by June 30, 1978. It is expected that this amendment will become effective when any final CPSA rule concerning benzene is effective.

ADDRESS: Comments should be sent to: Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207.

FOR FURTHER INFORMATION CONTACT:

Francine Shacter, Office of Program Management, Consumer Product Safety Commission, Washington, D.C. 20207, 301-492-6557.

SUPPLEMENTARY INFORMATION: In this issue of the FEDERAL REGISTER the Commission has proposed a rule (16 CFR Part 1307) under section 8 of the Consumer Product Safety Act (CPSA), declaring all consumer products, except gasoline and solvents or reagents for laboratory use, containing benzene as an intentional ingredient or as a contaminant at levels of 0.1 percent or greater to be banned hazardous products.

There is currently in existence a regulation under the Poison Prevention Packaging Act of 1970 (PPPA) at 16 CFR §1700.14(a)(15) requiring child-resistant packaging for prepackaged liquid solvents (such as removers, thinners, brush cleaners, etc.) for paints or other similar surface-coating materials (such as varnishes and lacquers) that contain 10 percent or more by weight of benzene, toluene, xylene, petroleum distillates, or combinations thereof, and that have a viscosity of less than 100 Saybolt Universal Seconds at 100° F.

It is apparent that many of the products covered by §1700.14(a)(15) will become banned hazardous products when proposed Part 1307, applicable to benzene-containing consumer products, except gasoline and laboratory benzene, is issued in its final form. Therefore, to eliminate any possible confusion which may arise from retaining a PPPA special packaging regulation for certain products which are now proposed to be banned hazardous products under the CPSA, the Commission proposes to amend §1700.14(a)(15) to indicate that it will not be applicable to products covered by the PPPA regulation that are also banned hazardous products under any final CPSA rule.

Since the purpose of this proposed amendment is to eliminate the possibility of confusion concerning requiring special packaging for products that are banned, the amendment is conditional upon Part 1307 being issued in final form and continuing in full force and effect. If, at any time, any requirement of Part 1307 relating to products within the scope of §1700.14(a)(15) is stayed, revoked, or set aside by judicial or other action, the amendment restricting the application of the PPPA special packaging requirement is to be withdrawn, and a FEDERAL REGISTER notice will be issued reinstating full applicability of the PPPA regulation. The Commission proposes that this amendment will become effective when any final ban under the CPSA concerning benzene becomes effective.

AMENDMENT

Accordingly, pursuant to provisions of the Poison Prevention Packaging Act of 1970 (Pub. L. 9-601; Secs. 2(4), 3, 5, 84 Stat. 1670-72, 15 U.S.C. 1471(4), 1472, 1474) and under authority vested in the Commission by the Consumer Product Safety Act (sec. 30(a), 86 Stat. 1231, 15 U.S.C. 2079(a)), the Commission proposes to amend 16 CFR §1700.14(a)(15) by adding the following language at the end of paragraph 15:

§1700.14 Substances requiring special packaging.

(a) Substances.

* * * * *

(15) * * * Since the Commission has issued a regulation under the Consumer Product Safety Act (CPSA) banning consumer products containing benzene as an intentional ingredient (see 16 CFR 1307), this paragraph is inapplicable to those benzene-containing consumer products which are covered by Part 1307. (This amendment is conditional upon Part 1307 continuing in full force and effect.)

Dated: May 15, 1978.

SADYE E. DUNN,
Acting Secretary, Consumer Product Safety Commission.

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